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KLINKEL, KORTNEY L.				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,262

Applicant(s)

CULLEN ET AL.

Examiner

Kortney L. Kinkel

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-13 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made of the remarks/amendments filed 8/26/2009. Claims 2, 8, 14-18 and 20 stand canceled. Claim 1 was amended. Claims 1, 3-7, 9-13 and 19 are pending.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3-7, 9, 12 and 19 under 35 U.S.C. 102(e) as being anticipated by Guo et al. (US 7252837) is withdrawn and has been re-written to account for the claim amendments.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3-13 and 19 under 35 U.S.C. 103(a) as being unpatentable over Cullen et al. WO 00/33893 is withdrawn and has been re-written to account for the claim amendments.

Double Patenting--Withdrawn

The provisional rejection of claims 1, 3-5, 9, and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/609964 and the provisional rejection of claims 1, 3-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-12 of copending Application No. 10/579850 are withdrawn in light of the filing of terminal disclaimers against these co-pending applications.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 was amended to recite the limitation "and from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance." The metes and bounds of the range of wound healing therapeutic applicant seeks patent protection for are unclear. The phrase "at least" implies an amount greater than 1%. The word "from" includes 1%. The claim is internally inconsistent. Additionally, the term "about" means that values outside 1% and 5% are desired. However, it is unclear how far reaching the word "about" spans as there is no definition for this word in the specification. Given the internal inconsistency in the claim and the ambiguity in the bounds of the word "about" it is completely reasonable that even 0% wound healing therapeutic substance is included by the claim. It is entirely unclear what lower limit applicant seeks patent coverage.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9-13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Independent claim 1 was amended to recite the limitation "and from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance." There is no support in the specification for these weight percents. Page 5, final paragraph recites from about 0.01 to about 5% by weight of one or more wound healing agents. Likewise, canceled claim 8 had previously recited from about 0.01 to about 5% by weight on a dry weight basis of one or more wound healing therapeutic substances. Furthermore there is absolutely no support for the phrase "**from about at least**" in the context of any range. The recitations of new matter must be removed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 9, 12 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Guo et al. (US 7252837).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 1 has been amended to add the limitation "from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance." Note that in lieu of the 112 2nd rejection above, the metes and bounds of this claim, and thereby all subsequent dependent claims is unclear. As addressed above, it is entirely reasonable given the uncertainty of the claim that even 0% wound healing therapeutic substance is included in all the claims.

Guo teaches a wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose (see Example 4). This wound dressing can additionally include a drug or a combination of pharmaceutical agents including analgesics, anti-infective agents, antibiotics, adhesion preventive agents, procoagulants and wound healing growth factors (col. 7, lines 54-63). More specifically, Example 4 discloses a patch comprising oxidized regenerated cellulose (ORC) and water soluble chitosan. The ORC is in the form of dispersed fibers (i.e. Surgicel Nu-Knit® fabric). Because the composition of Guo comprises all the requisite ingredients, it would

necessarily be capable of carrying out the intended use for topical application, as required by claim 4. The ORC and chitosan make up at least 50% by weight of the material on a dry weight basis, as per claims 6-7. As per instant claim 9, Example 4 states that the composition is a very flexible patch. Because no thickness is recited in claim 9, this patch can be considered a flexible film. With respect to claim 19, Guo teaches at col. 7, lines 54-63 that wound healing growth factors can be applied to the wound dressing as in the steps outlined in Example 4.

Response to Arguments

Applicant's arguments filed 8/26/2009 in response to the rejection of claims have been fully considered, but are moot in light of the new grounds of rejection necessitated by the amendment to claim 1. However, the examiner will address any issues still remaining.

Applicant argues that Guo et al. do not teach an "intimate mixture" of ORC and chitosan as defined in the specification. This argument is not persuasive.

Page 4 of the instant specification beginning at line 27 states "[p]referably, the intimate mixture comprises a mixed solution or dispersion of the chitosan and the oxidized cellulose in a suitable vehicle, such as a solvent, or a solid composition produced by removing solvent from such a solution or dispersion." This sentence constitutes a preference, not a definition. Nowhere else in the specification is the term "intimate mixture" defined. Additionally, Example 4 of Guo et al. can be considered to fall within this preference. In Example 4, a piece of Surgicel Nu-Knit® fabric was placed in a solution of water soluble chitosan. This mixture can be considered a dispersion.

The solvent is then lyophilized off. Therefore an intimate mixture between the two components would be formed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9-13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cullen et al. WO 00/33893.

Cullen teaches a sterile composition which can be used as a wound dressing (claim 19 and page 9, lines 6-10) comprising a polysaccharide selected from the group including oxidized celluloses and chitosans, and salts **and mixtures thereof** (claim 8) and a therapeutic peptide. Page 5, final paragraph states that chitosans and cellulose derivatives are equally effective polysaccharides for use in wound dressing compositions. Cullen further teaches that oxidized regenerated cellulose (ORC) is especially preferred (page 6, lines 13-14, also claim 9). Examples 2-4 are directed to compositions comprising ORC and Example 5 shows an example comprising chitosan. More specifically Examples 2 and 4 are directed to a combination of ORC and collagen, whereas Example 5 contains a mixture of collagen and chitosan. The ORC of Example 2 is in the form of fibers. Furthermore, page 3, lines 27-28 state that it is preferable that the ORC is in the form of fibers, which reads on instant claim 3.

With respect to newly added limitation to claim 1 requiring from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance, the 112 2nd rejection above is noted. The metes and bounds of the range of wound healing therapeutic substance is unclear. However, Cullen teaches that the above sterile compositions contain from 0.1 to 10000 ppm (i.e. 0.00001 to 1%) of a therapeutically effective peptide (p. 7, lines 27-33). A therapeutic peptide is a wound healing therapeutic substance. This range overlaps with the claimed range, especially given the 112 2nd rejection.

With respect to claim 4 which recites wherein said oxidized cellulose and chitosan are dispersed in a semi-solid or solid vehicle for topical application, Cullen teaches at page 8, lines 27-30 that the polysaccharide is preferably dispersed in a gel (i.e. semi-solid) or that the carrier is a solid matrix.

With respect to claims 6-7 which recite wherein the oxidized cellulose and chitosan together make up at least 25% or at least 50% by weight of the material on a dry weight basis, Cullen teaches in example 1 that the polysaccharide portion of the composition is at least 66% (the remainder of the weight 0-33% is made up of platelet derived growth factor). Furthermore, Cullen teaches a composition containing 80% by weight of ORC fibers (example 2).

Instant claim 13 recites wherein the wound dressing is sterile and packaged in a microorganism-impermeable container. Cullen teaches that preferably the sterile compositions are sterile packaged in a microorganism-impermeable container (page 9, 3rd paragraph).

Cullen does not specifically exemplify a composition comprising both oxidized cellulose and chitosan. However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC, because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts **and mixtures thereof** (claims 1 and 8). Furthermore, ORC and chitosan are art recognized functional equivalents. "It is

prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072. Accordingly, one of ordinary skill in the art would expect the combination of two art recognized materials useful in wound dressing compositions to yield a composition useful in wound dressings upon their combination.

Instant claim 9 states the wound dressing composition is a flexible film. In light of that addressed above and in addition to the fact that Cullen teaches a sterile composition in the form of a polymer film (claim 19), instant claim 9 is *prima facie* obvious over the teachings of the prior art due to the fact that a polymer film can be flexible. Due to the fact that the recited components of the claimed composition are substantially similar to those taught by Cullen in the prior art, there is a reasonable expectation that a film of the composition suggested by the prior art would also be flexible.

Instant claims 10 and 11 recite a range of oxidized cellulose to chitosan ratios respectively. Example 5 depicts a ratio of collagen to chitosan of 55/45. As addressed above, collagen, chitosan and ORC are art recognized functional equivalents, so it would be obvious to substitute collagen for ORC with a reasonable expectation for success. One would be motivated to do so since Cullen teaches that collagen and ORC are equally valid wound dressing materials. Further, it would have been in the capacity to one of ordinary skill in the art to mix the two polysaccharides in the stated ratios in

instant claims 10 and 11, based on the fact that both oxidized cellulose and chitosan have been shown to have the same function in this context. This is an optimization of ranges and as such is considered to be *prima facie* obvious when the general conditions of a claim, i.e. combining chitosan and oxidized cellulose for wound dressings, are disclosed in the prior art.

With respect to claim 19, Cullen teaches the steps of contacting a composition with a biological medium containing cell growth factors to bind the cell growth factors to the material and washing and drying the material having the cell growth factors bound thereto to form said active wound dressing material, see Procedure 1 beginning at page 20.

In conclusion, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC with a therapeutic wound healing substance because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts and mixtures thereof (claims 1 and 8). Cullen demonstrates that not only does a composition consisting of oxidized cellulose function as a wound dressing, but also a composition consisting of chitosan. Cullen also states that mixtures of the two polysaccharides are suitable for use (claim 8). Thus, combining two things that are each respectively recognized as being suitable in the prior art for a given purpose, one would have a reasonable expectation of success upon their combination.

The Examiner acknowledges Applicants' data in Figures 1-2 and has determined that this data is insufficient to overcome the instant rejection because the data contained in Figures 1-2 depict elastase and collagenase activity, respectively, versus time for a negative control (gauze), a positive control (collagen/ORC sponge) and instant claimed invention, ORC/chitosan and Applicants' claimed invention performs within error identical to the collagen/ORC sponge. This is what would be expected given the teachings of Cullen which unequivocally state that ORC, collagen and chitosan are equally effective wound composition materials. In the absence of evidence showing that collagen and not ORC is the active ingredient in the collagen/ORC sponge, Applicants' data further supports Examiner's arguments stated above. Namely that both oxidized cellulose and chitosan separately have been shown to be suitable for use in wound dressings, one of ordinary skill in the art would have a reasonable expectation of success upon their combination—as is shown in Applicants' Figures 1 and 2. In addition, Applicants' data in Figures 1-2 are not commensurate in scope with what is being claimed, because Applicants' data is limited to compositions comprising ORC/chitosan, whereas the majority of Applicants' claims do not require ORC.

Response to Arguments

Applicant's arguments filed 8/26/2009 with respect to the rejection of claims under Cullen et al. (WO 00/33893) have been fully considered, but are moot in light of the new grounds of rejection. However, the Examiner will address those arguments still relevant to the Cullen et al. reference.

Applicant argues that Cullen et al. does not teach, suggest or otherwise disclose a wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose. This argument is not persuasive.

Page 4 of the instant specification beginning at line 27 states "[p]referably, the intimate mixture comprises a mixed solution or dispersion of the chitosan and the oxidized cellulose in a suitable vehicle, such as a solvent, or a solid composition produced by removing solvent from such a solution or dispersion." This sentence constitutes a preference, not a definition. Nowhere else in the specification is the term "intimate mixture" defined. Upon studying the examples in the Cullen reference, it is clear that an intimate mixture between the combination of polysaccharides is obtained. All ingredients are swollen and mixed together in an aqueous slurry. A slurry can be considered a dispersion. For example, the teachings of example 5 refer to the combination of collagen and chitosan as a complex. Please note that the methods utilized in Cullen et al. are identical to those of the instant specification, therefore an intimate mixture is necessarily obtained.

Applicant further argues that "it is a surprising and unexpected result of the present invention that such intimate mixing results in maximum chemical complexation between the amine groups of the chitosan and the carboxylate groups of the oxidized cellulose (page 5, lines 1-2)." This argument is not persuasive. This reaction is by no means surprising or unexpected. It is well known that amines react with carboxylate groups to form amides. This reaction is thermodynamically very favorable, accordingly

one would expect the simple combination of oxidized cellulose and chitosan in solution to chemically complex (i.e. forming an intimate mixture).

Applicant further argues that "it is a surprising and unexpected result that the intimate mixture of the present invention has an excellent ability to bind to growth factors - in particular, platelet derived growth factor (PDGF) (page 10, lines 10-15)." Again, this finding is neither surprising or unexpected based on the teachings of Cullen et al. Cullen et al. teaches that both ORC and chitosan bind PDGR, see examples 2 and 5 respectively. Furthermore, page 5, final paragraph teaches that cellulose derivatives and chitosan are effective at stabilizing peptides against sterilization by ionizing radiation.

Applicant has provided no results to rebut the *prima facie* case of obviousness presented above.

Applicant further argues that Cullen et al. does not provide any teaching or suggestion or motivation for the skilled artisan to make or use a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose and having from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance. This argument is not substantiated with any support and is not persuasive. As addressed clearly in the above rejection, Cullen et al. make obvious the wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose and having from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance.

Applicant has provided no results to rebut the *prima facie* case of obviousness presented above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7252837. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are directed to a wound dressing comprising ORC and sodium carboxymethyl cellulose. The ratio of these two ingredients ranges from about 1:99 to about 20:80 which overlaps with the ranges of instant claims 10-11. The ORC is in the form of fibers. The difference between the

patented claims and the instant claims is that the patent utilizes sodium carboxymethyl cellulose rather than a chitosan as required by the instant claims. However, the final paragraph of column 4, continued onto column 5 teach that sodium carboxymethyl cellulose and chitosan and carboxymethyl chitosan are functional equivalents. This fact is further supported by the data presented in table 1 at columns 9-10. This table shows that ORC when mixed intimately with either sodium carboxymethyl cellulose or water soluble chitosan the same effect is observed (see Examples 4 and 5). Please note the above 112 2nd rejection regarding the amount of wound healing therapeutic substance present in the claims is unclear and the claims reasonably read on a dressing composition having no wound healing therapeutic.

Response to Arguments

Applicant's arguments regarding the ODP rejection of claims has been fully considered, but is not persuasive. Applicant argues that US patent 7252837 is currently assigned to Ethicon Inc. and this is not commonly owned with the instant application and therefore the rejection is improper. This argument is not persuasive. The instant application is also assigned to Ethicon Inc. Therefore, it appears as if the patent and the instant application are commonly owned. Furthermore, even if the conflicting patent and the instant application were not commonly owned at the time of the instant invention, an obviousness double patenting rejection would still be proper as they are now commonly owned. Please refer to MPEP 804, chart II-B.

Likewise the instant claims can be amended to overcome the rejection.

Conclusion

Claims 1, 3-7, 9-13 and 19 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Ashwin Mehta/
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